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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,454	03/05/2002	Gregory M. Podsakoff	0800-0009.08	9403

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,454	PODSAKOFF ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7-12,16,18 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12,16,18 and 20* is/are allowed.

6)☒ Claim(s) *1,3,4,7,8,10 and 11* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment after final received on 2/28/06 has been entered. Claims 17 and 19 have been canceled. Claims 1, 3-4, 7-12, 16, 18, and 20 are pending in the instant application. While applicant's cancellation of claims 17 and 19 overcomes the sole grounds of rejection of the claims presented in the final office action, the finality of the previous office action can been withdrawn in view of new grounds of rejection set forth in detail below. Claims 1, 3-4, 7-12, 16, 18, and 20 are therefore pending and under examination at this time. An action on the merits follows. Those sections of Title 35, US code, not included in this action can be found in the previous office action.

Claim Rejections - 35 USC § 102

The rejection of claims 17 and 19 are rejected under 35 U.S.C. 102(e) as being US Patent Application Publication 2002/0192189 A1 (Dec. 19, 2002), hereafter referred to as Xiao et al., is withdrawn in view of applicant's cancellation of claims 17 and 19.

The following new grounds of rejection for obviousness type double patenting apply.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-4, 7-8, and 10-11 are newly rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,610,290 (8/26/03), Podsakoff et al., hereafter referred to as the '290 patent. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Claims 1-8 of the '290 patent recite methods of delivering a selected gene to a heart of a mammalian subject, comprising: (a) providing recombinant adeno-associated virus (rAAV) virions which comprise an AAV vector, said AAV vector comprising said selected gene, wherein said, selected gene encodes a therapeutic protein; (b) administering said rAAV virions directly to said heart of said mammalian subject, wherein at least one cell of said heart is transduced by said rAAV virions; and (c) expressing said selected gene, wherein expression results in a therapeutic effect on a cardiomyopathy. The instant claims recite a broader method of delivering a selected gene to a muscle cell comprising (a) providing a recombinant adeno-associated viral (AAV) virion which comprises an AAV vector, said AAV vector comprising

said selected gene operably linked to control elements capable of directing the in vivo transcription and translation of said selected gene; and (b) introducing said recombinant AAV virion into said muscle cell or tissue, wherein said muscle cell or tissue is selected from the group consisting of smooth muscle, cardiac muscle and a cardiomyocyte. Both sets of claims comprise similar method steps; however, the claims of the '290 patent are limited to the transduction of heart cells whereas the instant claims comprise the transduction of any smooth muscle cell in addition to cardiac muscle and cardiomyocytes. It is well established that a species of a claimed invention renders the genus obvious. *In re Schaumann* , 572 F.2d 312, 197 USPQ 5 (CCPA 1978). Therefore, as a species of the instant claims, the methods of claims 1-8 of the '290 patent render the instant invention obvious.

Claims 1, 3-4, 7-8, and 10-11 are newly rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,391,858 (5/21/02) Podsakoff et al., hereafter referred to as the '858 patent. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Claims 1-14 of the '858 patent recite methods of administering recombinant adeno-associated virus (AAV) virions into the bloodstream of a mammalian subject, said method comprising: (a) providing AAV virions comprising a selected gene operably linked to expression control elements that provide for transcription and translation of the selected gene in a desired host cell in vivo; and (b) delivering said recombinant AAV virions to the bloodstream, whereby said selected gene is expressed at a level which provides a therapeutic effect in the mammalian subject. Dependent claims identify the selected gene as erythropoietin. The instant claims are

similar to the '858 patent but are limited to the delivery of the selected gene to smooth muscle, cardiac cells, and cardiomyocytes. Note as well that the instant claims recite wherein the recombinant AAV is "introduced" into a muscle cell, a step that includes any route of delivery such that a muscle cell as claimed is transduced including intravascular delivery. While the '858 claims do not specifically recite that smooth muscle, cardiac cells or cardiomyocytes are the "desired host cell", the specification of the '858 patent clearly states that muscle cells are the desired target cell for expressing the therapeutic protein and for systemic delivery and further teaches that muscle cells include smooth muscle in blood vessels and cardiomyocytes. Thus, while the '858 claims are broader than the instant claims, the specification clearly teaches the specific embodiment recited in the instant claims. As such, the claims of the '858 patent render obvious the instant claims as written.

Claims 1, 3-4, 7-8, and 10-11 are newly rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,211,163 (4/3/01) Podsakoff et al., hereafter referred to as the '163 patent. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Claims 1-8 of the '858 patent recite methods of administering recombinant adeno-associated virus (AAV) virions into the bloodstream of a mammalian subject, said method comprising: (a) providing AAV virions comprising a selected gene operably linked to expression control elements that provide for transcription and translation of the selected gene in a desired host cell in vivo; and (b) delivering said recombinant AAV virions to the bloodstream by intravenous injection, whereby said selected gene is expressed at a level which provides a

therapeutic effect in the mammalian subject. Dependent claims identify the selected gene as erythropoietin. The instant claims are similar to the '163 patent but are limited to the delivery of the selected gene to smooth muscle, cardiac cells, and cardiomyocytes. Note as well that the instant claims recite wherein the recombinant AAV is "introduced" into a muscle cell, a step that includes any route of delivery such that a muscle cell as claimed is transduced including intravenous delivery. While the '163 claims do not specifically recite that smooth muscle, cardiac cells or cardiomyocytes are the "desired host cell", the specification of the '163 patent clearly states that muscle cells are the desired target cell for expressing the therapeutic protein and for systemic delivery and further teaches that muscle cells include smooth muscle in blood vessels and cardiomyocytes. Thus, while the '163 claims are broader than the instant claims, the specification clearly teaches the specific embodiment recited in the instant claims. As such, the claims of the '163 patent render obvious the instant claims as written.

Allowable Subject Matter

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 12, 16, 18, and 20 remain allowable over the prior art of record at this time.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER